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January 9, 2009

Ms. Z. Ileana Martinez
Thompson Hine LLP
One Atlantic Center
1201 West Peachtree Street, NW - Suite 2200
Atlanta, Georgia 30309-3449

RE: ***Sonjia Lewis gamble and Anthony Gamble v. Advanced Medical Optics, Inc.,*** United States District Court, Northern District of Georgia, Atlanta Division, Civ. Action File No. 1 08-CV-2187

Dear Ms. Martinez:

Per our conversation yesterday, in reviewing over 45,000 documents produced by AMO in response to defendants discovery requests and the privilege log encompassing over 5000 pages of documents, AMO has asserted that no documents pertaining to its Root Cause Investigation have been produced, and that AMO has asserted the work product, and/or attorney client privilege as justification for its refusal to produce those documents.

It is clear from the privilege log that the information discerned from the Root Cause Investigation was shared with the FDA, CDC, Health Canada and perhaps other governmental agencies. The contention that the Root Cause Investigation was performed solely in anticipation of litigation and therefore protected from disclosure is unfounded. Among the documents AMO contends are not subject to disclosure are The Root Cause Analysis Report to Health Canada Re: Acanthamoeba Risk Associated with CMO, which is identified in Privilege Log 1 as AMO-GAM-20029240, and the Report for FDA Re: Root Cause Analysis of Acanthamoeba with CMP identified as AMO-GAM 20003257-AMO-GAM 2003268.

The information discerned via AMO's Root Cause Investigation has been shared with outside entities such as the FDA and Health Canada renders any privilege that might otherwise protect documents reflecting the Root Cause Investigation waived.

Further, it is clear that the reason for having conducted the Root Cause Investigation to begin with was not in anticipation of litigation, but rather to comply with governmental regulations promulgated by the FDA and Health Canada. The work product doctrine does not protect materials assembled in the ordinary course of business, pursuant to regulatory requirements, or for other non-litigation purposes. The mere fact that a defendant anticipates litigation will ensue does not automatically insulate investigative reports from discovery as work product.

Rather, if a business entity in the ordinary course of business conducts an investigation for its own purposes, such as to comply with regulatory requirements, that information is producible in civil pretrial discovery. The Root Cause Investigation was performed both in the course of AMO's business and for FDA compliance cannot be reasonably disputed.

Plaintiffs are entitled to those documents reflecting the Root Cause Investigation out of necessity. Plaintiffs have a substantial need for these documents for the preparation of their case and are unable, without undue hardship to obtain substantially equivalent materials by other means.

Given that the Root Cause Investigation was performed by AMO in the ordinary course of its business, regardless of whether it was also done in anticipation of litigation, and that it was done in order to comply with regulatory requirements of the FDA, Health Canada and others, and that the plaintiff have a substantial need for the Root Cause Investigation materials, and are unable to obtain the substantial equivalent of the materials by any other means, Plaintiffs hereby request that Defendant withdraw its objection to producing the root cause investigative documents and produce all documents in the privilege log pertaining to the Root cause investigation other than those prepared by counsel, or that are directed to counsel including but not limited to The Root Cause Analysis Report to Health Canada Re: Acanthamoeba Risk Associated with CMO, which is identified in Privilege Log 1 as AMO-GAM-20029240 the Report for FDA Re: Root Cause Analysis of Acanthamoeba with CMP identified as AMO-GAM 20003257-AMO-GAM 2003268.

Plaintiffs have forwarded this letter in a good faith effort to resolve the discovery dispute discussed above and in an effort to obtain these documents prior to the depositions of AMO's fact witnesses, which we are in the process of scheduling.

In the event we are unable to resolve the dispute, Plaintiffs will be forced to file a Motion To Compel and also ask the Court to either extend the deadline for the taking of fact witness depositions, or in the event they must move forward, allow for the resumption of those depositions once the Root Cause Documents are produced.

I look forward to hearing from you.

Very Truly Yours,

Keith L. Lindsay

KLL/emm

cc: Sonjia Lewis Gamble
Anthony Gamble

January 22, 2009

Keith L. Lindsay, Esq.
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Re: Gamble v. Advanced Medical Optics, Inc.
Civil Action File No. 1:08-CV-2187

Dear Keith:

We must respectfully disagree with your position, as stated in your letter of January 9, 2009, regarding the discoverability of AMO's root cause investigation. AMO's root cause investigation was initiated and directed by AMO's counsel immediately after the May 25, 2007 recall of Complete MPS in order to defend contact lens solution lawsuits which were expected to be filed and were in fact filed the first week of June 2007. Your repeated assertion that it was undertaken to comply with governmental regulations promulgated by the FDA and Health Canada, or "assembled in the ordinary course of business," is mistaken.

Your contention that the work product privilege has been waived is similarly off-base. A brief summary of certain of AMO's key root cause findings were presented to the FDA months thereafter, in response to later requests from the FDA, and the information was allowed to be and was designated as privileged and confidential under the Freedom of Information Act ("FOIA"). (5 U.S.C.A. § 552(b)4); Cozen O'Connor v. U.S. Dept. of Treasury (E.D. Pa. 2008) 570 F.Supp.2d 749, 776-778; 21 C.F.R. § 20.61.) That designation has been honored by the FDA and no public disclosure has occurred. Thus, there has been no waiver of privileges. (See e.g., Diversified Industries, Inc. v. Meredith, 572 F.2d 596, 606 (8th Cir. 1977) [voluntary disclosure of investigative report and certain other documents to the SEC constituted a waiver of privilege only with respect to the SEC]; In re Sealed Case, 676 f.2d 793, 818 (D.C. Cir. 1982) [purposes of work product privilege are not inconsistent with selective disclosure; work product protection not waived if privileged material is disclosed to party who shares common interest].)

We also disagree with your assertion that Plaintiffs have a "substantial need" for these documents. Plaintiffs have their own consultants and experts and are perfectly capable of conducting their own investigation into any alleged association between the product and acanthamoeba. Plaintiffs can and presumably already have undertaken their own causation investigation and are not entitled to purloin AMO's work product.

Accordingly, we disagree that Plaintiffs are entitled to AMO's root cause investigation documents and must decline your request that they be produced. Please feel free to contact me if you wish to discuss this further.

Sincerely,

Z. Ileana Martinez

ZIM/47885